

REMARKS

Applicants request reconsideration and withdrawal of the outstanding rejection based on the foregoing amendments and following remarks. Claims 1-31 have been cancelled and replaced with new claims 32-46. No new matter has been added.

Response to Rejections under 35 U.S.C. § 101

Claims 1-31 were rejected under 35 U.S.C. § 101. The Examiner asserted that the claims were directed to a use without setting forth any steps involved in the process. Applicants submit that claims 1-31 have been cancelled and new claims 32-40, directed to methods of treatment, have been added. Support for the new claims can be found on pages 9-11, the working examples, and the claims as originally filed. Applicants submit that the new claims satisfy the requirements of § 101 and recite positive method steps. Thus, Applicants respectfully request that the rejection be withdrawn.

Response to Rejections under 35 U.S.C. § 112

Claims 1-31 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner asserts that the term “buttermaking culture” is unclear because butter making *per se* does not involve any culture. Applicants submit that the term “buttermaking culture” is a translation of the German expression “Butterei-Kultur.” This term can also be appropriately translated as “butter culture,” which has been recited in the new claims. The term “butter culture” is a well established term of art. For example, in Toelle (U.S. 6,706,294), the term “butter culture” is frequently used. See

e.g., abstract, and claims 1 and 3 of Toelle. Thus, because the term “buttermaking culture” has been replaced with “butter culture,” which is an established term of art, Applicants submit that the claims are now clear and definite and respectfully request that the rejections be withdrawn.

The Examiner asserts that the term “wherein the increased blood sugar values are selected from fasting and/or postprandial blood sugar values” in claim 2 is unclear because fasting does not cause any increase in blood sugar level. Applicants submit that claim 2 has been cancelled, thereby rendering the rejection moot.

The Examiner asserts that the term “associated forms and/or performs” in claim 4 is unclear. Applicants submit that claim 4 has been cancelled, thereby rendering the rejection moot.

The Examiner asserts that the term “clinically manifests diabetes” in claim 5 is unclear. Applicants submit that claim 5 has been cancelled, thereby rendering the rejection moot. Applicants submit that claim 36 recites the term “clinically manifest diabetes,” which is defined on page 7, lines 22-26 of the specification and should therefore be clear and definite. Moreover, the term “clinically manifest diabetes” is a technical term. A form of diabetes is considered to be clinically manifest if the amount of insulin produced by the body is no longer sufficient to control the blood sugar level.

The Examiner asserts that the term “adiposity” in claims 8-9 is unclear.

Applicants submit that adiposity is the medical term for being abnormally overweight, which is characterized as an excessive accumulation of fat tissue in the body. Merriam-Webster’s medical dictionary defines adiposity as: “the quality or state of being fat.” The enclosed abstract of a paper by Zhou et al. (Biochem. Biophys. Res. Commun. 2005 September 30, 335 (3): 937-42) further exemplifies the scientific use of the word adiposity as a technical term. Applicants submit that “adiposity” is clearly understood by those of skill in the art and respectfully request that the rejection be withdrawn.

Response to Rejections under 35 U.S.C. § 102

Claims 1-31 were rejected under 35 U.S.C. § 102(b) as being anticipated by Tölle (WO/2001/010245- English equivalent: U.S. 6,706,294). The Examiner asserts that Tölle disclose the process of fermenting the distillers grains with yogurt or butter cultures (col. 1, lines 22-37), presenting the product in 200-250g ready to consume units (col. 1, lines 50-55), that the product is suitable for diabetics (col. 2, line 11), for slimming cures, recovery after operations, dietetic foods, treatment of diseases, intestinal function disorders (col. 2, lines 55-61), and for diabetics and weight reduction (col. 2, lines 47-48). Applicants submit that Tölle does not disclose a method for treating increased blood sugar values by administering a composition comprising distillers grains which, in addition to fermentation of yeast, also were fermented with yogurt culture and/or butter culture. Rather, Applicants submit that Tölle only discloses the use of double fermented distillers grains as supplemental dietary products (see for example title, claim 1, column 3, lines 11 to 16). The only message a person skilled in

the art would have derived from Tölle is that double fermented distillers grain, which is healthy for everybody including diabetics, is even more suited for diabetics due to the low amount of sugars and carbohydrates in the composition (see for example column 2, lines 9 to 12, and lines 44 to 48). Tölle does not disclose the use of double fermented grain for lowering the blood sugar in diabetics. There is no link in Tölle between the administration of double fermented grain and treating diabetics. This is exemplified by the fact that insofar as Tölle enumerates diseases which could be "treated" by administering a product of the present invention (see column 2, lines 55 to 61), the list does not mention diabetes. Instead, it is only stated that distillers grains can be employed as a supplementary diet during slimming cures, during recovery after operations or illness, as dietetic foods for the treatment of amino acid deficiency diseases, pancreatic functional disorders, carbohydrate addition diseases and intestinal functional disorders. The fact that Tölle describes double fermented distillers grains to be suitable, e.g., for the treatment of pancreatic functional disorders does of course not mean that it will lower increased blood sugar values of diabetes patients.

Tölle is directed to improving a process for producing foods, dietetic foods and food additives based on distillers grains as specified in DE 39 04 962 C (column 1, lines 8 to 13). It is reported that this prior art process does not provide optimal results in terms of taste and smell (see column 1, lines 13 to 16). Tölle found a process for preparing food, dietetic foods and food additives based on distillers grains which no longer exhibit disturbing flavors (see column 2, lines 4 to 7). Applicants submit that a

person skilled in the art does not obtain any motivation from Tölle to treat patients suffering from increased blood sugar values using the presently claimed composition.

The working examples of the present specification demonstrate a method resulting in significant improvements in patients in terms of a reduction of fasting insulin level, HOMA-IR and blood sugar value, even after elimination of the interfering factor "weight." Thus, the experimental data provided in the above patent application demonstrates the development of a method for treating patients by administering an increased blood sugar value lowering composition. It was unexpected that the composition for use in the presently claimed method would have an increased blood sugar value lowering effect (as mentioned on page 4, lines 21-24 of the specification). Accordingly, Applicants submit that the present claims are not anticipated or rendered obvious by Tölle and respectfully request that the rejections be withdrawn.

Conclusions

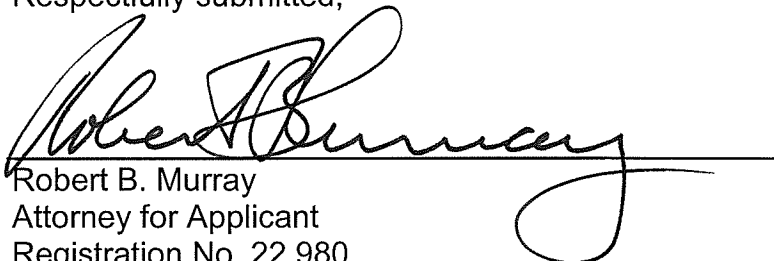
In view of the above amendments and remarks hereto, Applicants believe that all of the Examiner's rejections set forth in the December 24, 2009 Office Action have been fully overcome and that the present claims fully satisfy the patent statutes. Applicants, therefore, believe that the application is in condition for allowance.

The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

By

A handwritten signature in black ink, appearing to read "Robert B. Murray", is written over a horizontal line. The signature is fluid and cursive.

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